UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/478,188	01/05/00	SHEN	B	2500.128US1

HM22/0119

TOM HUNTER
SKJERVEN MORRILL MACPHERSON, LLP
25 METRO DRIVE
SUITE 700
SAN JOSE CA 95110

EXAMINER	
KERR, K	
ART UNIT	**PAPER NUMBER**
1652	8

DATE MAILED: 01/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/478,188	Applicant(s) Shen et al.
	Examiner Kathleen Kerr	Group Art Unit 1652

☒ Responsive to communication(s) filed on *12/4/00* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-71* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-71* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Application Status

1. Claims 1-71 are pending in the instant application. Applicants response to the Notice to Comply with the sequence rules has been received; further action is required by Applicants to comply with the sequence rules (see below).

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

SuperGroup A (Groups 1-49). Claims 1-9, 18-23, drawn to a nucleic acid encoding any one of the 49 C-1027 biosynthesis polypeptides, related expression vectors, and related host cells classified in class 536, subclass 23.7.

SuperGroup B (Group 50). Claims 10-14, drawn to the entire gene cluster which encodes polypeptides sufficient to direct the assembly of C-1027 or analogues thereof, classified in class 435, subclass 23.1.

SuperGroup C (Groups 51-100). Claims 15-17, drawn to any one of the 49 C-1027 biosynthesis polypeptides, classified in class 435, subclass 183.

SuperGroup D (Groups 101-150). Claims 24-50, drawn to methods of chemically modifying a biological molecule using any one of the 49 C-1027 biosynthesis polypeptides, classified in class 435, subclass 183.

SuperGroup E (Groups 151-158). Claims 51-53, drawn to methods of synthesizing a chromaprotein type enediyne core using particular polypeptides (8 are specifically noted in Claim 53), classified in class 435, subclass 76.

SuperGroup F (Groups 159-166). Claims 54-56, drawn to methods of synthesizing a deoxysugar using particular polypeptides (8 are specifically noted in Claim 56), classified in class 435, subclass 72.

SuperGroup G (Groups 167-172). Claims 57-60, drawn to methods of synthesizing a beta amino acid using particular polypeptides (6 are specifically noted in Claim 59), classified in class 435, subclass 106.

SuperGroup H (Group 173). Claims 61-68, drawn to methods of synthesizing an enediyne or analogue thereof using the C-1027 biosynthesizing gene cluster, classified in class 435, subclass 76.

SuperGroup I (Groups 174-180). Claims 69-71, drawn to methods of making a cell resistant to enediyne or analogue thereof using polynucleotides encoding particular polypeptides (7 are specifically noted in Claim 70), classified in class 435, subclass 471.

A total of 180 independent or distinct Groups is noted above.

3. The inventions are distinct, each from the other because of the following reasons:

The Examiner will first describe distinctness between SuperGroups, then will describe distinctness among the members (if more than one) of each SuperGroup; all other Groups are

considered unrelated, for example the nucleic acid encoding ORF 13 and the polypeptide encoded by ORF 25, because of their distinct structural and functional characteristics.

SuperGroup A and SuperGroup B are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed for patentability because, for example, Claim 10 is not claimed by a SEQ ID NO which contains each and every SEQ ID NO of the open reading frames of Claim 1. The subcombination has separate utility such as transporting glycerol phosphate by the polypeptide encoded by ORF 2, for example. Thus, every member of SuperGroup A is patentably distinct from the member of SuperGroup B.

The nucleic acids of SuperGroup A are related to the polypeptides of SuperGroup C by virtue of the fact that the nucleic acids encode the related polypeptides in a one-to-one relationship. The nucleic acids have utility for the recombinant production of the polypeptide in a host cell. Although the nucleic acids and the polypeptides are related, they are distinct inventions because the polypeptide product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, the nucleic acids can be used for processes other

than the production of polypeptides, such as nucleic acid hybridization assays. Therefore, the related members of SuperGroups A and C are patentably distinct.

The nucleic acids of SuperGroup A and the methods of SuperGroups D-G are related because the nucleic acids encode the related proteins used in the methods. However, the nucleic acids are not disclosed as being used in said methods as either reagents or products, particularly because the proteins used in the methods can be purified from natural sources. Thus, the related members of SuperGroup A are patentably distinct from the related members of SuperGroups D-G.

The nucleic acids of SuperGroup A and the related methods of SuperGroups H-I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids can be used in materially different processes of using that product, for example in the recombinant production of the encoded proteins. Thus, the related members of SuperGroup A are patentably distinct from the related members of SuperGroups H-I.

The gene cluster of SuperGroup B is related to the polypeptides of SuperGroup C by virtue of the fact that parts of the gene cluster encode the individual polypeptides. Parts of the gene cluster have utility for the recombinant production of the polypeptide in a host cell. Although the gene cluster and the polypeptides are related, they are distinct inventions because

the polypeptide product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, the gene cluster can be used for processes other than the production of polypeptides, such as in recombinant methods of synthesizing enediyne in a host cell. Therefore, the SuperGroup B is patentably distinct from every member of SuperGroup C.

The gene cluster of SuperGroup B and the methods of SuperGroups D-G are related because parts of the gene cluster encode the proteins used in the methods. However, the gene cluster is not disclosed as being used in said methods as either reagents or products, particularly because the proteins used in the methods can be purified from natural sources. Thus, SuperGroup B is patentably distinct from the every member of SuperGroups D-G.

The gene cluster of SuperGroup B and the methods of SuperGroups H-I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the gene cluster can be used in materially different processes of using that product, for example in the recombinant production of the encoded proteins. Thus, SuperGroup B is patentably distinct from every member of SuperGroups H-I.

The polypeptides of SuperGroup C and the related methods of SuperGroups D-G are related as product and process of use. The inventions can be shown to be distinct if either or both

of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides can be used in materially different processes of using that product, for example in the production of antibodies to the encoded proteins. Thus, the related members of SuperGroup C are patentably distinct from the related members of SuperGroups D-G.

The polypeptides of SuperGroup C and the methods of SuperGroups H-I are related because the polypeptides are encoded by the related nucleic acids used in the methods. However, the polypeptides are not disclosed as being used in said methods as either reagents or products. Thus, the related members of SuperGroup C are patentably distinct from the related members of SuperGroups H-I.

The methods using the same polypeptides in SuperGroups D-G are related because they have this reagent in common. However, other reagents, such as the polyketide precursor, are distinct. Additionally, the products are distinct as are the method steps. Thus every member of SuperGroups D-G are patentably distinct from every other member.

The methods using the same nucleic acids in SuperGroups H-I are related because they have this reagent in common. However, other reagents and products are distinct; and these methods have distinct method steps. Thus every member of SuperGroups H-I are patentably distinct from every other member.

The methods of SuperGroups D-G are related to the methods of SuperGroups H-I by virtue of the fact that the proteins used in D-G are encoded by the nucleic acids used in H-I. However, these are distinct methods using different reagents and different method steps to produce distinct products. Thus, every member of SuperGroups D-G is patentably distinct from every member of SuperGroups H-I, each from the other.

In addition to every member of each SuperGroup being distinct or unrelated to every member of every other SuperGroup, members within the defined SuperGroups are also distinct.

The 49 members of SuperGroup A are related because either they encode a polypeptide involved in enediyne biosynthesis or because they encode an open reading frame within a gene cluster involved in enediyne biosynthesis. Said members are distinct, each from the other, because each nucleic acid sequence has its own open reading frame with a distinct primary, secondary, and tertiary structure with a distinct function. No genus to encompass the 49 members of SuperGroup A has been set forth in functional AND structural features. Thus, every member of SuperGroup A is patentably distinct, each from the other.

SuperGroup B has only one member.

The 49 members of SuperGroup C are related because either they are a polypeptide involved in enediyne biosynthesis or because they are a hypothetical protein (having an open reading frame) encoded by an open reading frame within a gene cluster involved in enediyne biosynthesis. Said members are distinct, each from the other, because each polypeptide sequence has its own distinct primary, secondary, and tertiary structure with a distinct function. No genus

to encompass the 49 members of SuperGroup C has been set forth in functional AND structural features. Thus, every member of SuperGroup C is patentably distinct, each from the other.

The members of SuperGroups D-G and H-I are distinct, each from the other, for the reasons described above for the polypeptides (D-G) or the nucleic acids (H-I) which are used in the methods.

Notice of Possible Rejoinder

4. The Examiner notes that if polypeptide claims of SuperGroup C are found directed to an allowable product, then related method claims of SuperGroups D-G, which are directed to the process of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also MPEP 821.04, *In re Ochiai,* and *In re Brouwer*). The Examiner also notes that if nucleic acid claims of SuperGroup A or B are found directed to an allowable product, then related method claims of SuperGroups H-I, which are directed to the process of using the patentable product would now be rejoined.

If allowable product in	then rejoin related method claims from
SuperGroup C	SuperGroups D-G
SuperGroup A	SuperGroups H-I
SuperGroup B	SuperGroups H-I

Sequence Compliance

5. Applicants response to the Notice to Comply with the sequence rules has been received; however, the computer-readable form of the sequence listing has an error. The error report produced by the Scientific and Technical Information Center is enclosed to assist Applicants in correcting the error.

Election

6. Applicants are advised that the reply to this requirement MUST include an election of the invention to be examined, even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

7. For a response to this Office action to be complete, Applicants MUST

a. elect a Group for prosecution, and

b. correct the error in the sequence listing.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Kathleen M. Kerr whose telephone number is (703) 305-1229. The Examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

KMK

January 16, 2001